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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,510	03/17/2004	Srinka Ghosh	10030936-1	5441

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EXAMINER

FORMAN, BETTY J

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 11/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/803,510

Applicant(s)

GHOSH ET AL.

Examiner

BJ Forman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, Claims 1-11 in the reply filed on 24 August 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 12-21 are canceled.

Claims 1-11 are under prosecution.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 4 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 is indefinite for the recitation "each interior feature" because the recitation lacks proper antecedent basis in Claim 1. It is suggested the claim be amended to provide proper antecedent basis.

Claim 6 is indefinite because the claim is drawn to a reference pattern at one or more opposing diagonal corners of the microarray. The claim encompasses a single reference pattern. It is unclear how a single reference pattern can be in opposing corners i.e. in more than one location.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 5 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Empedocles et al (U.S. Patent Application Publication No. 2002/0028457, published 7 March 2002).

Regarding Claim 1, Empedocles et al disclose a microarray comprising a substrate (§ 116), a number of features comprising probe molecules, each feature located at a different position on the substrate (§ 29), and a reference pattern that comprises a number (e.g. one) of pattern blocks comprising an arrangement of one or more nearest-neighbor positive control features around a central feature (e.g. “alignment spots” in upper right hand corner of Fig. 8 A, which are around the adjacent feature of interest, § 108 and Fig. 8).

The claim further describes an intended use for the array features i.e. comparison of computed positions, indicates feature extractability problem. The courts have stated that a claim containing a “recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus” if the prior art apparatus teaches all the structural limitations of the claim. Ex parte Masham, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987). Empedocles et al disclose all the structural limitations of the claimed microarray. Therefore the intended use recited in the claim does not differentiate the claimed microarray from that of Empedocles et al.

Regarding Claim 5-6, Empedocles et al disclose the microarray wherein the reference pattern is positioned at a corner of the microarray (Fig. 8A).

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6. Claims 1-3, 5-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Yakhini et al (EP 1162572, published 12 December 2001).

Regarding Claim 1, Yakhini et al disclose a microarray comprising a substrate, a number of features comprising probe molecules, each feature located at a different position on the substrate (Abstract), and a reference pattern that comprises a number of pattern blocks comprising an arrangement of one or more nearest-neighbor positive control features around a central feature (e.g. background, 3102-3110 surrounding features 3112-3120, ¶ 67 and Fig. 31).

Regarding Claim 2, Yakhini et al disclose the pattern includes each possible arrangement of nearest neighbor around a central positive control and negative control i.e. the background completely surrounds the central feature and the features comprise positive and/or negative controls (¶ 67).

Regarding Claim 3, Yakhini et al disclose the pattern comprising a two-dimensional array of pattern blocks (Fig. 31).

Regarding Claim 5-6, Yakhini et al disclose the microarray wherein the reference pattern is positioned at a corner of the microarray (i.e. 3102/3112 are in the corner of a 3 x 3 pattern Fig. 31).

7. Claims 1, 3, 5-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Lockhart et al (U.S. Patent No. 6,344,316, issued 5 February 2002).

Regarding Claim 1, Lockhart et al disclose a microarray comprising a substrate, a number of features comprising probe molecules, each feature located at a different position on the substrate (Abstract), and a reference pattern that comprises a number of pattern blocks (Fig. 2b) comprising an arrangement of one or more nearest-neighbor positive control features (i.e. PM probes adjacent to MM probes which differ by a single nucleotides (Column 8, lines 21-

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67) and thereby form a pair of nearest neighbor features) around a central feature (i.e. central cross, Column 10, lines 49-52 and Fig. 2a).

Regarding Claim 3, Lockhart et al disclose the microarray wherein the reference pattern comprises a two-dimensional array of pattern blocks (Fig. 2a-b).

Regarding Claim 5-6, Lockhart et al disclose the microarray wherein the reference pattern is positioned at a corner of the microarray (i.e. dividing the array as illustrate in Fig. 2b, each corner provides a reference pattern comprising PM probes adjacent to MM probes).

Regarding Claim 7, Lockhart et al disclose a kit comprising the microarray of Claim 1 (Column 4, line 66-Column 5, line 9).

Regarding Claim 8, Lockhart et al disclose a kit comprising a microarray wherein the microarray comprises features, each having a different oligonucleotide (Column 4, line 66-Column 5, line 32).

Regarding Claim 9, Lockhart et al disclose a kit comprising the microarray of Claim 1 (Column 4, line 66-Column 5, line 9) and further comprising reference targets (Column 60, line 55-Column 61, line 14).

Regarding Claim 10, Lockhart et al disclose the kit comprises all possible oligonucleotides of a specific length e.g. all possible 6 mers (Column 60, line 55-Column 61, line 14). All possible 6-mers would provide for hybridization to all sequences on the array and thereby meet the structural limitations of the claim.

Regarding Claim 11, Lockhart et al further disclose the kit comprising instructions (Column 61, lines 10-14).

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Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-3, 5-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rothberg et al (U.S. Patent No. 6,355,423, issued 12 March 2002) in view of Lockhart et al (U.S. Patent No. 6,344,316, issued 5 February 2002).

Regarding Claim 1, Rothberg et al disclose a microarray comprising a substrate, a number of features comprising probe molecules, each feature located at a different position on the substrate (Abstract), and a reference pattern that comprises a number of pattern blocks (Fig. 5A) comprising an arrangement of one or more nearest-neighbor positive control features (i.e. error checking cells adjacent to observational array (Column 51, line 13-Column 52, line 60). Rothberg et al are silent regarding positioning the error checking sequences central to the observational array. However, Lockhart et al teach a similar array comprising PM and MM probes wherein a control feature is central to the array whereby target hybridization is normalized (Column 10, lines 49-52 and Column 31, line 43-Column 32, line 11). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the configuration of Lockhart to the error cell of Rothberg. One of ordinary skill in the art would have been motivated to do so for the normalizing the signal adjacent to the control as taught by Lockhart (Column 10, lines 49-58).

Furthermore, the courts have stated that absent evidence to the contrary, a particular configuration of a known device is a matter of choice which would have been obvious to one skilled in the art. *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966) (The court held that the configuration of the claimed disposable plastic nursing container was a matter of choice

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which a person of ordinary skill in the art would have found obvious absent persuasive evidence that the particular configuration of the claimed container was significant.). Hence, absence evidence to the contrary, the claimed configuration having control features around a central feature would have been an obvious variation of the Rothberg microarray.

Regarding Claim 2, Rothberg et al teach the microarray comprising a complete checking station having all degrees of degeneracy (Column 51, lines 28-39). While they do not teach all possible arrangements of error cells, absence evidence to the contrary, the claimed configuration having control features around a central feature would have been an obvious variation of the Rothberg microarray.

Regarding Claim 3, Rothberg et al disclose the microarray wherein the reference pattern comprises a two-dimensional array of pattern blocks (Fig. 5a).

Regarding Claim 5-6, Rothberg et al disclose the microarray wherein the reference pattern is positioned at a corner of the microarray (e.g. #512, Fig. 5a).

Regarding Claim 7, Rothberg et al disclose a kit comprising the microarray of Claim 1 (Column 10, line 54-Column 11, line 11).

Regarding Claim 8, Rothberg et al disclose a kit comprising a microarray wherein the microarray comprises features, each having a different oligonucleotide (Fig. 5a, Column 50, lines 15-56).

Regarding Claim 9, Rothberg et al disclose a kit comprising the microarray of Claim 1 and further comprising reference targets (Column 10, line 54-Column 11, line 11).

Regarding Claim 10, Rothberg et al disclose the kit comprises the microarray of Claim 1 and further teach the microarray comprises all possible oligonucleotides of a specific length (Column 50, lines 15-56). All possible sequences of a given length would provide for hybridization to all sequences on the array and thereby meet the structural limitations of the claim.

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Regarding Claim 11, Rothberg et al further disclose the kit comprising instructions (Column 11, lines 6-10).

10. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rothberg et al (U.S. Patent No. 6,355,423, issued 12 March 2002) in view of Lockhart et al (U.S. Patent No. 6,344,316, issued 5 February 2002) and further in view of Walt et al (U.S. Patent No. 6,327,410, issued 4 December 2001).

Regarding Claim 4, Rothberg and Lockhart disclose the microarray of Claim 1 as discussed. Rothberg et al further teach the features are beads (Column 56, lines 43-64) but they are silent regarding hexagonal arrangement of the features. However, Walt et al teach a similar array comprising probes immobilized on beads wherein bead-immobilized probes are arranged in hexagonally on a fiber optic substrate (Fig. 6, Column 17, lines 11-19) thereby providing an extremely high density array (Column 5, lines 22-31). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the hexagonal arrangement of Walt et al to the beads of Rothberg et al for the expected benefit of providing an extremely high density array as desired in the art (Walt et al, Column 5, lines 22-31).

Conclusion

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

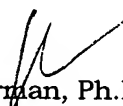
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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.


BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
October 26, 2006